



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**WASHINGTON, D.C. 20460**

**OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION**

**MEMORANDUM**

**DATE:** May 9, 2018

**SUBJECT:** Response to registrant's rebuttal to Agency's comments and recommendations concerning efficacy study to evaluate the repellency of end use product, PIGNX CAULKING GEL, containing 0.0357 % w/w Capsaicin as its active ingredient. EPA Registration No. 84418-1.

<b>Decision Number:</b>	538053
<b>DP Number:</b>	445798
<b>EPA File Symbol Number:</b>	84418-1
<b>Chemical Class:</b>	Biochemical
<b>PC Code:</b>	070701
<b>CAS Number:</b>	404-86-4
<b>Active Ingredient Tolerance Exemptions:</b>	Non-food
<b>MRID Numbers:</b>	504982-01

**FROM:** Clara Fuentes, Entomologist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

**TO:** Menyon Adams, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

## **ACTION REQUESTED**

Technology Science Group, Inc. on behalf of Bio-Repellent Scientific Industries, Inc., is submitting a rebuttal letter, dated April 26, 2018, in response to the Agency's deficiency letter, dated April 12, 2018, with comments and recommendations concerning adequacy of study report, MRID 504982-01, to evaluate repellency of end use product, PIGNX CAULKING GEL, against rats in support of label amendment to add rats to the product label.

## **BACKGROUND INFORMATION**

The study report in MRID 504982-01 is based on a previously submitted study protocol, MRID 501576-01, that was reviewed by the Agency on Feb 27, 2017. In its review, the Agency provided the following recommendations to upgrade the study protocol to acceptable:

### **1. Agency comment:**

If the objective of the study is to evaluate repellency of the product against rats when applied to surfaces, data will have to be generated on the efficacy of the product on different materials, porous and non-porous surfaces; i.e, wood, plastic, ceramic, and metal. Otherwise, the label should restrict use of the product to the type of material on which the product is tested.

Registrant's response:

1.a) The registrant has revised the Rat Repellent Sublabel, Detour Gel for Rodents, to limit application of the product to plastic surfaces.

1.b) Label instructions for use on rats has also been revised to limit frequency of applications every 6 hour intervals.

### **2. Agency comment:**

A total number of 80 rats were employed in testing choice and non-choice tests. The 80 rats were divided in 4 groups of 20 (10 males: 10 females) rats and randomly assigned to the treatments. The tests consisted of a choice test with its corresponding negative control, and a non-choice test with its corresponding negative control. So, each test had 2 treatments, a treated group and an untreated control group. Twenty rats (10 males and 10 females) were randomly assigned to negative (untreated) control for choice treatment in the choice test. So, 40 rats (20 males and 20 females) were randomly assigned to either control or treatment group for the choice test. Each treatment (treated and control) in the choice test was replicated only once with a group of 20 rats each.

The non-choice test was done the same way with a different group of 40 randomly (20 males and 20 females) assigned rats. The non-choice test consisted of 2 treatments, one treated group of 20 randomly assigned rats, and a negative (untreated) control of 20 randomly assigned rats. Each treatment, treated and untreated control group in the non-choice test consisted of 20 rats, and each treatment was replicated once. This means that the for both tests, choice and non-choice, the sample size was 20 rats for each treatment, treated and untreated control, within each test.

80 rats divided in 2 groups of 40  
40 rats for choice test, divided into 2 group of 20, and  
40 rats for non-choice test, divided into 2 groups of 20.  
20 rats for control group in choice test, and  
20 rats for treated group in choice test.  
20 rats for treated group in non-choice test, and  
20 rats for control group in non-choice test.

Therefore, each treatment, control and treated group, in choice test was replicated once with a sample size of 20 rats. Likewise, each treatment, control and treated group, in non-choice test was replicated once with a sample size of 20 rats/ treatment replications. The 20 rats per treatment are not the number of treatment replications. The 20 rats per treatment are the number of observations per treatment replication; that is, 20 independent observations per treatment replication. In this study, there is only 1 replication. Each treatment was replicated once with a sample size of 20 rats.

Registrant response:

2.a) The registrant insists that each observation in the sample constitutes a treatment replication and thus, the number of replications is 20.

Agency Comment concerning number of replications per treatment:

Each treatment, control and treated group, in choice test was replicated once with a sample size of 20 rats. Likewise, each treatment, control and treated group, in non-choice test was replicated once with a sample size of 20 rats/ treatment replications. The 20 rats per treatment are not the number of treatment replications. The 20 rats per treatment are the number of observations per treatment replication; that is, 20 independent observations per treatment replication. In this study, there is only 1 replication. Each treatment was replicated once with a sample size of 20 rats.

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20 rats for treated group in choice test.  
20 rats for treated group in non-choice test, and  
20 rats for control group in non-choice test.

#### AGENCY RECOMMENDATIONS

**The Agency is asking for 3 treatment replications as a minimum to verify test results, because the test results reported in this study (summarized below) are based on one treatment replication only. Please, add one more retreatment replication with 10 rats per treatment to verify the results from the study.**

Results from **choice test**, control group, in Table 16 on pp. 77-78 (MRID 505812-01), show that **mean crossings of males of females combined into either left or right untreated T arms of the control test arena was  $78.05 \pm 19.48$** . Mean crossings of females and males combined into the **treated T arm of the treated test arena was  $15.70 \pm 18.55$** .

The **mean number of times the rats crossed the treated arm and reached food and water in the treated group of the choice test was  $13.50 \pm 10.58$** . The mean number of times that rats crossed the **untreated arm and reached food and water in the treated group of the choice test was  $48.25 \pm 21.22$** . The **mean number of times control rats crossed either untreated left or right arm of the control T and reached food and water was  $36.40 \pm 11.24$  and  $38.60 \pm 12.59$** , respectively. **These results show preference for the untreated site. Table 3, on pg. 15 (MRID 505812-01) shows statistically significant difference ( $p < 0.0001$ ) between mean number of crossings in control and treated groups for choice test.**

Results from control male and female rats combined in non-choice test, Table 17 on pp. 79-80 (MRID 505812-01), show that mean number of crossings was  $99.45 \pm 40.84$ , and the mean number of control males and females combined reaching food and water was  $56.45 \pm 15.47$ . For the treated group, the mean number of crossings thru treated barrier was  $27.25 \pm 25.21$ . The mean number of male and female rats reaching food and water across treated barrier was  $37.80 \pm 18.70$ . **The mean number of crossings treated barrier ( $27.25 \pm 25.21$ ) was significantly different from control ( $99.45 \pm 40.84$ ) ( $p < 0.0001$ ).**

These results are based on one treatment replication only. The Agency requests from 3 to 5 treatment replications, minimum, depending on variability.

cc: Clara Fuentes, RAL Menyon Adams, BPPD Chron File, IHAD/ARS  
FT, PY-S: May, 9, 2018